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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,484	08/24/2001	Fabrice Duprat	1201-CIP-DIV-00	3868
35811	7590	11/02/2005	EXAMINER	
IP GROUP OF DLA PIPER RUDNICK GRAY CARY US LLP			YAEN, CHRISTOPHER H	
1650 MARKET ST			ART UNIT	
SUITE 4900			PAPER NUMBER	
PHILADELPHIA, PA 19103			1643	

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/939,484	Applicant(s) DUPRAT ET AL.	
	Examiner Christopher H. Yaen	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

RE: DUPRAT et al

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/10/2005 has been entered.
2. Claims 1-8 and 16-23 are canceled without prejudice or disclaimer.
3. Claims 9-15 are pending and examined on the merits.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Maintained - 35 USC § 101 & 112, 1st paragraph

5. The rejection of claims 9-15 under 35 USC § 101 as lacking a substantial and specific utility is maintained for the reasons of record. Applicant argues that the instantly claimed invention has a specific and substantial well established utility. To support such assertions, applicant argues that because TASK is expressed in many different tissues, such as in neurons, and is indicated as behaving "like a K⁺-selective hole", that the instantly claimed protein may be used in a process of screening for the identification of substances that modulate the function of TASK. Applicant further

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contends that such "substances" would be useful for the treatment of disease of the heart or nervous system, such as epilepsy, heart and vascular disease, etc. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

Applicant directs the examiner to paragraph [0069] to indicate that TASK is expressed in many different tissues, however, this is mRNA expression and not protein expression and therefore supplies little information with regard to the actual expression of the protein in such tissue. Secondly, as indicated in the previous office action dated 2/8/2005, the use of the instantly claimed TASK protein of SEQ ID No: 4 for the "screening" of substances that modulate the function of TASK is not a specific nor substantial utility, because such as utility as argued applies to many other proteins or receptors. Further, even assuming that the "screening" methods are specific, applicant has not established that the TASK protein is in fact involved in any of the disease (i.e. for the treatment of epilepsy, heart and vascular diseases) with which the alleged specific utility would be useful in identifying a modulating substance. Therefore no specific or substantial utility can be associated with the claimed TASK protein.

Applicant further argues that at the time the invention was filed, the art taught that pH constituted a natural modulator of neuronal activity. Applicant supports this argument by citing an abstract by Chesler *et al.* Applicant further contends that K⁺ channels are associated with neuronal cell death/survival and supports this assertion by citing Heurtaeux *et al.* and Yu *et al.* Applicant concludes from these arguments that given the information disclosed in the specification and the state of the art at the time

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the invention was filed, that TASK protein function is associated with neuronal activity and also neuronal death/survival based on the structure of the claimed protein.

Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

Applicant's specification provides expression data regenerated from mRNA expression profiles. However, nowhere in the specification does that applicant actually show the expression of the TASK protein as it would exist endogenously in the tissue. Applicant provides a post filing date reference to indicate that the TASK protein is in fact involved in K⁺ neuron apoptosis, however, the exemplified utilities as discussed and disclosed in the specification does not provide a predictable nexus between the treatment of disease associated with TASK and the regulation of K⁺. Thus, in the absence of any correlation between the claimed TASK protein with any known disease or disorder, any information obtained from various expression profiles only serves as the basis for further research on the observation itself. Thus even knowing that the TASK protein may be involved in K⁺ regulation, the utility of screening for agents is still viewed as being a general non specific utility.

The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. . . . [u]nless and until a process is refined and developed to this point-where *specific* benefit exists in currently available form- there is insufficient justification for permitting an applicant to engross what may

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prove to be a broad field. . . . a patent is not a hunting license. . . .[i]t is not a reward for the search, but compensation for its successful conclusion.

Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

The rejection of claims 9-15 under 35 USC 112, 1st paragraph as lacking an enabling disclosure based on the lack of a specific and substantially well established utility is also maintained for the reasons of record.

New Arguments

Claim Rejections - 35 USC § 112, 1st paragraph

6. Claims 9-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case has only set forth a a TAsK protein of SEQ ID No: 4, wherein there are only two P domains and 4 transmembrane segments, and therefore the written description is not commensurate in scope to the claims that read on functional equivalents derivatives having at least 85% identity to SEQ ID No: 4, wherein there are more that one P domains and three-more, than six transmembrane segments, as claimed. The following *written description* rejection is set forth herein.

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Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117). The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

The claims recite a “functionally equivalent derivatives having at least 85% identity to SEQ ID No: 4” as part of the invention. However, there does not appear to be an adequate written description in the specification as-filed of the essential structural feature that are representative of the broad genus sequences or derivatives claimed. The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 “Written Description” Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 3rd column).

Applicant does not appear to have reduced to practice a representative number of sequences or functional derivatives that are at least 85% identical to SEQ ID No: 4. The specification does not provide any specific core structure nor identification of any specific function or a correlation between structure and function of the functional derivatives claimed. Neither has Applicant provided a sufficient written description of any structure that may be correlated with the desired function of a derivative of the TASK protein of SEQ ID No: 4. Thus the genus of compounds encompassed by this term is extensive and the artisan would not be able to recognize that Applicant was in possession of the invention as now claimed.

Consequently, Applicant was not in possession of the instant claimed invention. See Regents of the University of California v. Eli Lilly and Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). Adequate written description of genetic material "requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention." Id. 43 USPQ2d at 1404 (quoting Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606). The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter of the claim. Id. 43 USPQ2d at 1406. A description of what the genetic material does, rather than of what it is, does not suffice. Id. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001. Applicant is invited to point to clear support or specific examples of the claimed invention in the specification as-filed.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1643
October 28, 2005


CHRISTOPHER YAEN
PATENT EXAMINER